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INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Date Submitted: October 30, 2003

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Sheet 1 of 6

Complete if Known

Application Number	08/982,284
Filing Date	12/01/1997
First Name of Inventor	Henryk Lubon
Group Art Unit	1632
Examiner Name	Michael C. Wilson

Attorney Docket Number

030523-0141

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
ML	A1	Fukamizu et al. "Tissue-Specific Trans-Activation of Renin Gene By Targeted Expression of Adenovirus E1a in Transgenic Mice," <i>Biochemical and Biophysical Research Communications</i> , 199(1):183-190 (02/28/94) ©Academic Press, Inc.	
	A2	Fukuoka, et al., "Assignment of the Tamm-Horsfall protein/uromodulin gene (<i>Umod</i>) to mouse chromosome bands 7F1-F2 and rat chromosome bands 1q36→q37 by <i>in situ</i> hybridization," <i>Cytogenet Cell Genet</i> , 79:241-242 (1997) ©S. Karger AG Basel.	
	A3	Haider et al., "Electron Microscopic Localization of LacZ Expression in the Proximal Convoluted Tubular Cells of the Kidney in Transgenic Mice Carrying Chimeric Erythropoietin/lacZ Gene Constructs," <i>Journal of Structural Biology</i> 118:220-225 (1997) ©Academic Press.	
	A4	Inase et al., "Isolation of Human Aquaporin 3 Gene," <i>The Journal of Biological Chemistry</i> 270(30):17913-17916 (July 28, 1995) ©The American Society for Biochemistry and Molecular Biology, Inc.	
	A5	Jiang et al., "Expression of osteopontin mRNA in normal and stone-forming rat kidney," <i>Urol Res</i> 26:389-294 (1998) ©Springer-Verlag.	
	A6	Kim et al., "Kidney-specific activity of the bovine uromodulin promoter," <i>Transgenic Research</i> 12:191-201 (2003) © Kluwer Academic Publishers.	
	A7	Lin et al., "Precursor Sequence Processing, and Urothelium-specific Expression of a Major 15-kDa Protein Subunit of Asymmetric Unit Membrane," <i>The Journal of Biological Chemistry</i> 269(3):1775-1784 (January 21, 1994) © The American Society for Biochemistry and Molecular Biology, Inc.	
	A8	Lin et al., "A tissue-specific promoter that can drive a foreign gene to express in the suprabasal urothelial cells of transgenic mice," <i>Proc. Natl. Acad. Sci. USA</i> 92:679-683 (January 1995)	
ML	A9	Mullins et al., "Studies on the Regulation of Renin Genes Using Transgenic Mice," <i>Clin. And Exper. Hyper-Therapy and Practice</i> A10(6):1157-1167 (1988) ©Marcel Dekker, Inc.	

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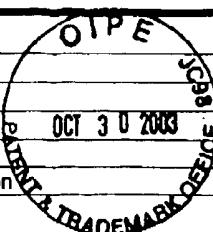
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	A10	Pennica et al., "Identification of Human Uromodulin as the Tamm-Horsfall Urinary Glycoprotein," <i>Science</i> 236:83-88 (April 3, 1987)	
	A11	Pook et al., "Localization of the Tamm-Horsfall glycoprotein (uromodulin) gene to chromosome 16p12.3-16p13.11," <i>J. Hum. Genet</i> 57:285-290 (1993).	
	A12	Rai et al., "Cloning of rat and mouse aquaporin-2 gene promoters and identification of a negative cis-regulatory element," <i>Am. J. Physiol.</i> 273(2 pt 2):F264-73 (August 27, 1997) ©American Physiological Society.	
	A13	Semenza et al., "Cell-type-specific and hypoxia-inducible expression of the human erythropoietin gene in transgenic mice," <i>Proc. Natl. Acad. Sci. USA</i> , 88:8725-8729 (October 1991)	
	A14	Semenza, Gregg L., "Erythropoietin Gene Expression in Transgenic Mice and Human Hepatoma Cells," <i>Annals New York Academy of Sciences</i> , 718:41-49 (April 15, 1994)	
	A15	Shiraga et al., "Inhibition of calcium oxalate crystal growth <i>in vitro</i> by uropontin: Another member of the aspartic acid-rich protein superfamily," <i>Proc. Natl. Acad. Sci. USA</i> 89:426-430 (January 1992)	
	A16	Sigmund et al., "Tissue and Cell Specific Expression of a Renin Promoter-Reporter Gene Construct in Transgenic Mice," <i>Biochemical and Biophysical Research Communications</i> , 170(1):344-350 (July 16, 1990) ©Academic Press, Inc.	
	A17	Simonet et al., "In the Absence of a Downstream Element, the Apolipoprotein E Gene Is Expressed at High Levels in Kidneys of Transgenic Mice," <i>The Journal of Biological Chemistry</i> 265(19):10809-10812 (July 5, 1990) © The American Society for Biochemistry and Molecular Biology, Inc.	
	A18	Stricklett et al., "Targeting Collecting Tubules Using the Aquaporin-2 Promoter," <i>Exp. Nephrol</i> 7:67-74 (1999) ©S. Karger AG.	

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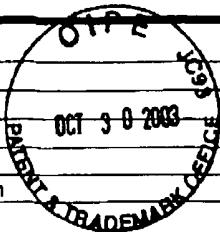
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<i>MW</i>	A19	Uchida et al., "Isolation of Human Aquaporin-CD Gene," <i>The Journal of Biological Chemistry</i> 269(38):23451-23455 (September 23, 1994) ©The American Society for Biochemistry and Molecular Biology, Inc.	
	A20	Umenishi et al., "Isolation of the Human Aquaporin-1 Promoter and Functional Characterization in Human Erythroleukemia Cell Lines," <i>Genomics</i> 47:341-349 (1998) ©Academic Press.	
	A21	Yu et al., "Bovine and Rodent Tamm-Horsfall Protein (THP) Genes: Cloning, Structural Analysis, and Promoter Identification," <i>Gene Expr.</i> 4(1-2):63-75 (1994) ©Cognizant Comm. Corp.	
	A22	Zbikowska et al., "The use of uromodulin promoter to target production of recombinant proteins into urine of transgenic animals," <i>Transgenic Research</i> 11:425-435 (2002) ©Kluwer Academic Publishers.	
	A23	Zbikowska et al., "Uromodulin promoter directs high-level expression of biologically active human α ₁ -antitrypsin into mouse urine," <i>Biochem J.</i> 365:7-11 (2002) ©Biochemical Society	
	A24	Zhu et al., "Isolation of mouse THP gene promoter and demonstration of its kidney-specific activity in transgenic mice," <i>Am. J. Physiol Renal Physiol</i> 282:F608-F617 (2002)	
	A25	Zhu et al., "Renal tubule-specific expression and urinary secretion of human growth hormone: a kidney-based transgenic bioreactor," <i>Transgenic Research</i> 12:155-162 (2003) © Kluwer Academic Publishers.	
	A26	Archibald, et al., <i>Proc. Natl. Acad. Sci</i> 87:5178-5182 (1990)	
<i>MW</i>	A27	Badgett et al., <i>Urol Int</i> 61:72-75 (1998)	

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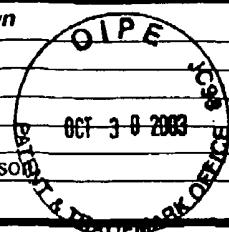
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	08/982,284
Date Submitted: October 30, 2003 (use as many sheets as necessary)		Filing Date	12/01/1997
		First Named Inventor	Henryk Lubon
		Group Art Unit	1632
		Examiner Name	Michael C. Wilson
Sheet	4	of	6
Attorney Docket Number 030523-0141			



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<i>HL</i>	A28	Ebert et al., <i>Bio/Technology</i> 9:835-838 (1991)	
	A29	Enrst et al., "Dokl Akad Nauk 345:555-558 (1995)	<i>RECEIVED</i>
	A30	Gordon et al., <i>Bio/Technology</i> 5:1183-1187 (1987)	<i>NOV 06 2003</i>
	A31	Howle et al., "Cell Tissue Res 274(1):15-19 (1993)	<i>TECH CENTER 1600/2900</i>
	A32	Kleinjan et al, <i>Transgenic Res</i> 7:85-94 (1998)	
	A33	Massoud et al., <i>J. Biotechnol</i> 18:193-204 (1991)	
	A34	Meade et al., <i>Bio/Technology</i> 8:443-446 (1990)	
<i>AM</i>	A35	Pittius et al. <i>Proc. Natl. Acad Sci</i> 85:5874-5878 (1988)	

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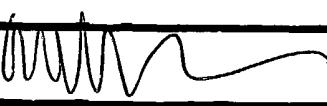
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Sheet	5	of	6	O I P E U.S. PATENT & TRADEMARK OFFICE OCT 30 2003	

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ML	A36	Reitman et al., <i>Nature</i> 348(6303):749-752 (December 20-27 1990)				
ML	A37	Taboit-Dameron et al., <i>Transgenic Res</i> 8:223-235 (1999)				RECEIVED NOV 06 2003 TECH CENTER 1600/2900
ML	A38	Yu et al., <i>Gene Expr</i> 4:63-75 (1994)				
ML	A40	Lubon et al., "Transfusion Medicine Reviews X(2): 131-143 (1996)				
ML	A41	Germain et al., 2001 <i>Not considered. Bad citation</i>				
ML	A42	Haidar et al., "Differential expression of <i>lacZ</i> in the liver and kidney of transgenic mice carrying chimeric <i>lacZ</i> -erythropoietin gene constructs with or without its 1.2 kb 3'-flanking sequence," <i>Nucleic Acids Research</i> 24(18):3621-3628 (1996) © Oxford University Press.				
ML	A43	Hijiya et al., "Cloning and characterization of the human osteopontin gene and its promoter," <i>BioChem J</i> 303:255-262 (1994).				
ML	A44	Hozawa et al., American Physiological Society, C1695-C1702 (1996)				

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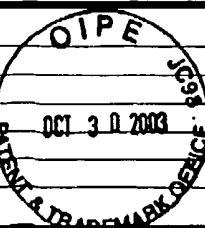
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MJN	A45	Kohri et al., "Structure and Expression of the mRNA Encoding Urinary Stone Protein (Osteopontin)," <i>The Journal of Biological Chemistry</i> 268(20):15180-15184 (July 15, 1993). ©The American Society for Biochemistry and Molecular Biology, Inc.	
	A46	Nelson et al., "Expression of an AQP2 Cre recombinase transgene in kidney and male reproductive system of transgenic mice," <i>Am. J. Physiol</i> 275(1 Pt 1):C216-226 (July 1998) ©The American Physiological Society.	
	A47	Sakuma et al., "Difference of osteopontin gene regulation between bone and kidney," <i>J. Orthop Sci.</i> 8:361-366 (2003) ©The Japanese Orthopedic Association.	
	A48	Smith et al., "Accumulation of Human Apolipoprotein E in the Plasma of Transgenic Mice," <i>The Journal of Biological Chemistry</i> 265(25):14709-14712 (September 5, 1990) ©The American Society for Biochemistry and Molecular Biology, Inc.	
	A49	Wen et al., "Urinary Excretion of Aquaporin-2 in Rat Is Mediated by a Vasopressin-Dependent Apical Pathway," <i>J. Am Soc Nephrol</i> 10:1416-1429 (1999) ©American Society of Nephrology.	
AMN	A50	Zharkikh et al., "Renal principal cell-specific expression of green fluorescent protein in transgenic mice," <i>Am J. Physiol Renal Physiol</i> 283:F1351-F1364 (2002)	

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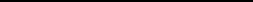
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WW	A41	Germain et al., "New Elements In Human Renin Promoter Involved in Cell-Specific Expression," <i>Clinical and Experimental Pharmacology</i> 28:1056-1059 (2001).	

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